



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-19-0573; Docket No. CDC-2019-0034]

**Proposed Data Collection Submitted for Public Comment and
Recommendations**

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS) .

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled National HIV Surveillance System (NHSS). This data collection is for continuation of the National HIV Surveillance System which provides the primary population-based data used to describe the epidemiology of HIV in the United States including adult/adolescent and pediatric HIV case reporting, case report evaluations and updates, laboratory updates, deduplication activities, investigation reporting and evaluation, cluster

reporting, perinatal HIV exposure reporting, and annual reporting of the standards evaluation report.

DATES: CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE *FEDERAL REGISTER*]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2019-0034 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

National HIV Surveillance System (NHSS) (OMB Control No. 0920-0573 Expiration 06/30/2019) - Revision - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is authorized under Sections 304 and 306 of the Public Health Service Act (42 USC 242b and 242k) to collect information on cases of human immunodeficiency virus (HIV) and indicators of HIV disease and HIV disease progression including AIDS. Data collected as part of the National HIV Surveillance System (NHSS) are the primary data used to monitor the extent and characteristics of the HIV burden in the United States. HIV surveillance data are used to describe trends in HIV incidence, prevalence and characteristics of infected persons and used widely at the federal, state, and local levels for planning and

evaluating prevention programs and health-care services, and allocate funding for prevention and care.

As science, technology, and our understanding of HIV have evolved, the NHSS has been updated periodically. CDC in collaboration with health departments in the 50 states, the District of Columbia, and U.S. dependent areas, conducts national surveillance for cases of HIV infection that includes critical data across the spectrum of HIV disease from HIV diagnosis, to AIDS, the end-stage disease caused by infection with HIV, and death. In addition, this national system provides essential data to estimate HIV incidence, monitor patterns in HIV drug resistance and genetic diversity and identify and respond to clusters of recent and rapid transmission, as well as provide information on perinatal exposures in the United States. The CDC surveillance case definition has been modified periodically to accurately monitor disease in adults, adolescents and children and reflect use of new testing technologies and changes in HIV treatment. Information is then updated in the case report forms and reporting software as needed.

In 2018, CDC implemented activities under a new cooperative agreement PS18-1802: Integrated HIV Surveillance and Prevention Programs for Health Departments. The purpose of PS18 1802 is to implement a comprehensive HIV surveillance and prevention

program to prevent new HIV infections and achieve viral suppression among persons living with HIV. In particular, the activities funded under the announcement promote and support improving health outcomes for persons living with HIV through achieving and sustaining viral suppression, and reducing health-related disparities by using quality, timely, and complete surveillance and program data to guide HIV prevention efforts. These goals are in accordance with the CDC's and national prevention goals, including the President's new initiative to End the HIV Epidemic in America. This information collection request revision includes activities to continue national surveillance program activities and align with program priorities under the new cooperative agreement (PS18-1802).

The revisions requested in this extension include minor modifications to currently collected data elements and forms (including the Adult Case Report Form (ACRF) and the Pediatric Case Report Form (PCRF)), modifications to data system variables used to summarize geocoded address data collected as part of the geocoding and data linkage activities, addition of new cluster report forms for health departments to report on progress for HIV cluster response activities and addition of investigation reporting and evaluation activities to account for additional data reported as part of these activities. No changes are being requested to data elements collected on the Perinatal HIV

Exposure Reporting (PHER) form, but the number of jurisdictions (respondents) completing the form has been reduced. Minor changes to the information collected in the standards evaluation report form (SER) are also requested to align with changes in program activities under PS18-1802. Finally, we have updated our burden estimates to more accurately reflect current data collection practices (e.g., adjusting the average burden per response for electronic laboratory updates and including a separate line item for deduplication activities previously included with case report evaluations and including new cumulative deduplication activities).

CDC provides funding for 59 jurisdictions to provide adult and pediatric HIV case reports. Health department staff compile information from laboratories, physicians, hospitals, clinics and other health care providers to complete the HIV adult and pediatric case reports. CDC estimates that approximately 854 adult HIV case reports and three pediatric case reports are processed by each health department annually.

These data are recorded using standard case report forms either on paper or electronically and entered into the electronic reporting system. Updates to case reports are also entered into the reporting system by health departments as additional information may be received from laboratories, vital statistics, or additional providers. Evaluations are also

conducted by health departments on a subset of case reports (e.g. re-abstraction, validation). CDC estimates that on average approximately 86 evaluations of case reports, 2353 updates to case reports and 9410 updates of electronic laboratory test data will be processed by each of the 59 health departments annually. In addition, all 59 health departments will conduct routine deduplication activities for new diagnoses and cumulative case reports. CDC estimates that health departments on average will follow-up on 2741 reports as part of deduplication activities annually. Case report information compiled over time by health departments is then de-identified and forwarded to CDC on a monthly basis to become part of the national HIV surveillance database.

When necessary additional information may be reported by health departments for monitoring and evaluation of health department investigations including activities identifying persons who are not in HIV medical care and linking them to HIV medical care (e.g., Data-to-Care activities) and other services and identifying and responding to clusters. CDC estimates health departments will on average process 901 responses related to investigation reporting and monitoring annually.

Clusters of HIV are groups of persons related by recent, rapid transmission, for which rapid response is needed in order to intervene to interrupt ongoing transmission and prevent

future HIV infections. Health departments may detect clusters through multiple means, including through routine analyses of Surveillance data and other data reported to the NHSS. Data on clusters of recent and rapid HIV transmission in the United States will be collected to monitor situations necessitating public health intervention, assess health department response, and evaluate outcomes of intervention activities. These summary data will be collected through quarterly cluster report forms that will be completed by health departments for clusters that they have identified and for which they are actively conducting response activities. Health departments will complete an initial cluster report form when a cluster is first identified, a cluster follow-up form for each quarter in which the cluster response remains active and a cluster close-out form when cluster response activities are closed or at annual intervals while a cluster response remains active. Completion of forms will be determined by the number of clusters detected. Health departments that do not identify recent and rapid clusters of HIV transmission will not complete any cluster report forms, while some jurisdictions will detect multiple recent and rapid clusters of HIV transmission, necessitating the completion of multiple cluster report forms. CDC estimates on average health departments will provide information for 2.5 cluster initial

cluster reports, five Cluster Follow-up Form reports, and 2.5 Cluster Close-out Form reports annually.

Perinatal HIV surveillance and prevention activities with HIV exposure reporting and perinatal services coordination is an integrated approach to advancing the progress toward perinatal HIV elimination goals. A subset of 16 health departments in the most affected jurisdictions will be reporting using the Perinatal Exposure Reporting (PHER) form to monitor and evaluate perinatal HIV prevention efforts. An estimated 197 reports containing perinatal exposure data elements will be processed on average annually by each of the 16 health departments reporting data collected as part of PHER. These supplemental data are also reported monthly to CDC.

The Standards Evaluation Report (SER) is used by CDC and Health Departments to improve data quality, interpretation, usefulness, and surveillance system efficiency, as well as to monitor progress toward meeting surveillance program objectives. The information collected for the SER includes a brief set of questions about evaluation outcomes and the collection of laboratory data that will be reported one time a year by each 59 health departments.

Table 1. Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response	Total Burden (in hours)

				(in hours)	
Health Departments	Adult HIV Case Report	59	854	20/60	16795
Health Departments	Pediatric HIV Case Report	59	3	20/60	59
Health Departments	Case Report Evaluations	59	86	20/60	1691
Health Departments	Case Report Updates	59	2353	2/60	4627
Health Departments	Laboratory Updates	59	9410	0.5/60	4627
Health Departments	Deduplication Activities	59	2741	10/60	26953
Health Departments	Investigation Reporting and Evaluation	59	901	1/60	886
Health Departments	Initial Cluster Report Form	59	2.5	1	148
Health Departments	Cluster Follow-up Form	59	5	30/60	148
Health Departments	Cluster Close-out Form	59	2.5	1	148
Health Departments	Perinatal HIV Exposure Reporting (PHER)	16	197	30/60	1576
Health Departments	Annual Reporting: Standards Evaluation Report (SER)	59	1	8	472
Total					58129

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